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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/192,792	06/24/2016	Daniel D. Von Hoff	37901-715.331	3589
96600	7590	06/28/2018	EXAMINER	
WOMBLE BOND DICKINSON (US) LLP			LIN, JERRY	
ATTN: IP Docketing				
P.O. Box 7037			ART UNIT	
Atlanta, GEORGIA 30537-7037			PAPER NUMBER	
UNITED STATES OF AMERICA			1631	
			NOTIFICATION DATE	
			DELIVERY MODE	
			06/28/2018	
			ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

15/192,792

Applicant(s)

Von Hoff et al.

Examiner

JERRY LIN

Art Unit

1631

AIA Status

No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 June 2016.
 - A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) Claim(s) 1-17 is/are pending in the application.
 - 5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 1-17 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) All b) Some** c) None of the:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____
- 3) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 4) Other: _____

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Status of the Claims

Claims 1-17 are under examination.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more.

Claims 1-17 are directed to method identifying at least one therapeutic agent for an individual with cancer. As described in *Alice Corp. Pty. Ltd. V. CLS Bank Int'l*, 573 U.S., 134 S. Cr. 2347, 110 U.S.P.Q.2d 1976 (2014), a two-step analysis is required in considering the patent eligibility of the claimed subject matter. The first step requires determining if the claimed subject matter is directed to a judicial exception. The instant claims require the assaying molecular targets, comparing molecular profile test values with a reference value to identify a biological state, identifying a therapeutic agent where the biological state indicates a likely benefit from the therapeutic agent, and generating a report of the biological state. In the instant case, the step of comparing molecular profile test values with a reference value to identify a biological state is a natural correlation between molecular targets and a biological state. Thus, the instant claims are drawn to the judicial exception of a natural correlation. Furthermore, the courts have found comparing data to also be drawn to the judicial exception of an abstract idea. (See *Classen Immunotherapies Inc. v. Biogen IDEC* 659 F.3d 1057, 100 U.S.P.Q.2d 1492 (Fed Cir. 2011)). Thus, the instant claims are drawn to a judicial exception.

The second part of the analysis requires determining if the claims include additional elements that are sufficient to amount to significantly more than the judicial exception. The instant claims recite the additional elements of assaying molecular targets, a computer database, program code, inputting values, generating a report. According to the specification, on pages 20-46, assaying molecular targets is well-known, conventional and routine. In addition, a computer database, program code, inputting values, and generating a report, are well-known, conventional, and routine functions or components of a computer (See specification, page 47, paragraphs 00187-00189; MPEP §§2106.05 (d), 2106.05(f) and 2106.05(g)). In addition, the recitation of the specific markers to be used in the abstract idea does not transform the abstract idea into a non-abstract idea. (See *buySAFE, Inc. v Google, Inc.* 765 F.3d 1350, 112 U.S.P.Q.2d 1093 (Fed.Cir.2014)). Furthermore, the elements taken as a combination are also well-known, conventional and routine, since the elements are merely specifying the types of data for a data gathering step. Thus, the instant claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception.

Dependent claims 2- 4 recite additional elements of a computer system. However, remotely inputting data, using an internet connection or presenting a report in an electronic or paper format are well-known, conventional, and routine functions of a generic computer. (See MPEP §§2106.05 (d), 2106.05(f) and 2106.05(g)) Reciting well-known, conventional, and routine functions of a generic computer is not sufficient to transform a judicial exception into patent eligible subject matter.

Dependent claims 5-14 and 17 recite additional elements regarding the data used and the source of data. However, describing the data and the source of the data is sufficient to transform the judicial exception into patent eligible subject matter (See *buySAFE, Inc. v Google, Inc.* 765 F.3d 1350, 112 U.S.P.Q.2d 1093 (Fed.Cir.2014); MPEP §2106.05 (g)).

Dependent claims 15 and 16 recite particular assays. However, these assays are well-known, conventional, and routine data gathering processes (specification pages 20-46; MPEP §2106.05 (d)). Reciting well-known, conventional, and routine data-gathering processes is not sufficient to transform a judicial exception into patent eligible subject matter.

Examiner's Note:

3. The closest prior art is Kallioniemi et al. (U.S. 2005/0244880) who teaches a method of assaying for molecular targets (paragraphs 0080-0010 and 086), comparing the profile to a normal reference (paragraphs 0008 and 0101), accessing a drug database for therapies for the targets (paragraph 0089), and generating a report (paragraphs 00889 and 0161). However, Kallioniemi et al. do not teach the molecular targets of AR, BRAF, CTNNB1, EGFR, ERBB2, ESR1, KIT, KRAS, MET, MLH1, PDGFRA, PDGFRB, PIK3CA (PI3K), PTEN, and TOP1 or that the report includes the efficacy of each drug.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on M, Tu, Th, F, 5:30am-4pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative

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